

117TH CONGRESS
2D SESSION

S. 4090

To improve transparency and the availability of information regarding dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to list dietary supplements with the Food and Drug Administration.

IN THE SENATE OF THE UNITED STATES

APRIL 26, 2022

Mr. DURBIN (for himself and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve transparency and the availability of information regarding dietary supplements by amending the Federal Food, Drug, and Cosmetic Act to require manufacturers of dietary supplements to list dietary supplements with the Food and Drug Administration.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Dietary Supplement
5 Listing Act of 2022”.

1 **SEC. 2. REGULATION OF DIETARY SUPPLEMENTS.**

2 (a) IN GENERAL.—Chapter IV of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
4 ed by inserting after section 403C of such Act the fol-
5 lowing:

6 **SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIRE-
7 MENT.**

8 “(a) IN GENERAL.—Each dietary supplement shall
9 be listed with the Secretary in accordance with this sec-
10 tion.

11 “(b) LISTING SUBMISSIONS.—

12 “(1) IN GENERAL.—Each responsible person,
13 or, if the responsible person is a foreign entity, the
14 United States agent, shall submit to the Secretary
15 in accordance with this section the following infor-
16 mation for each dietary supplement that will be mar-
17 keted:

18 “(A) Any proprietary name of the dietary
19 supplement and the statement of identity, in-
20 cluding brand name and specified flavors, if ap-
21 plicable.

22 “(B) The full name, address, and tele-
23 phone number for the responsible person, and
24 the name and e-mail address of the owner, op-
25 erator, or agent in charge of the responsible
26 person.

1 “(C) The full name, address, telephone
2 number, and e-mail address for the United
3 States agent, if the responsible person is a for-
4 eign entity.

5 “(D) The full business name and address
6 of all locations at which the responsible person
7 manufactures, packages, labels, or holds the di-
8 etary supplement.

9 “(E) An electronic copy of the label for the
10 dietary supplement, and an electronic copy of
11 the package insert, if any.

12 “(F) A list of all ingredients in the dietary
13 supplement required to appear on the label
14 under sections 101.4 and 101.36 of title 21,
15 Code of Federal Regulations, including—

16 “(i) the amount per serving of each
17 listed ingredient, if such information is re-
18 quired to appear on the label; and

19 “(ii) if required by section 101.36 of
20 title 21, Code of Federal Regulations, the
21 percent of the daily value of each listed in-
22 gredient.

23 “(G) The number of servings per container
24 for each container size.

25 “(H) The conditions of use.

1 “(I) Warnings and precautions.

2 “(J) Statements regarding major food al-
3 lergens, as defined in section 201(qq) of the
4 Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 321(qq)).

6 “(K) The dosage form, such as pill, cap-
7 sule, liquid, or powder.

8 “(L) Any claim that—

9 “(i) characterizes the relationship of
10 any nutrient which is of the type required
11 by section 403(q)(1) or section (q)(2) to be
12 in the label or labeling of the food to a dis-
13 ease or a health-related condition; or

14 “(ii) is subject to notification under
15 section 403(r)(6) that appears in the sup-
16 plement’s labeling.

17 “(M) The unique dietary supplement iden-
18 tifier for the product, provided in accordance
19 with paragraph (3).

20 “(2) FORMAT.—A listing submitted under this
21 section shall be in such electronic form and manner
22 as the Secretary may prescribe. The Secretary shall
23 promptly confirm, electronically, receipt of a com-
24 plete listing under this section.

1 “(3) UNIQUE LISTING IDENTIFICATION NUM-
2 BERS.—

3 “(A) IN GENERAL.—The Secretary shall
4 establish a unique dietary supplement identifier
5 system that shall be used by the responsible
6 person under this section.

7 “(B) RESERVATION OF NUMBERS.—The
8 system shall allow a responsible person to re-
9 serve multiple dietary supplement identifier
10 numbers in advance of listing.

11 “(C) USE REQUIREMENT.—Any unique di-
12 etary supplement identifier shall be used only in
13 connection with the product for which the iden-
14 tifier was used during the listing process.

15 “(4) SUBMISSION DATES.—A responsible person
16 under this section shall report to the Secretary the
17 listing information described in paragraph (1) pur-
18 suant to the following timelines:

19 “(A) IN GENERAL.—

20 “(i) EXISTING DIETARY SUPPLE-
21 MENTS.—In the case of a dietary supple-
22 ment that is being offered in interstate
23 commerce on the date that is 18 months
24 after the date of enactment of the Dietary
25 Supplement Listing Act of 2022, a listing

1 for each such dietary supplement formula-
2 tion introduced or delivered for introduc-
3 tion into interstate commerce by the re-
4 sponsible person for commercial distribu-
5 tion shall be submitted by the responsible
6 person with the Secretary under this sec-
7 tion not later than 60 days after the date
8 that is 18 months after the date of enact-
9 ment of such Act.

10 “(ii) NEW DIETARY SUPPLEMENTS.—
11 In the case of a dietary supplement that is
12 not being offered in interstate commerce
13 on the date that is 18 months after the
14 date of enactment. of the Dietary Supple-
15 ment Listing Act of 2022, a listing for
16 each such dietary supplement formulation
17 introduced or delivered for introduction
18 into interstate commerce by the responsible
19 person for commercial distribution which
20 has not been included in any listing pre-
21 viously submitted by the responsible person
22 to the Secretary under this section shall be
23 submitted to the Secretary prior to intro-
24 ducing the dietary supplement into inter-
25 state commerce.

1 “(B) REFORMULATIONS.—A listing of each
2 dietary supplement formulation introduced by
3 the responsible person for commercial distribu-
4 tion that has a label that differs for such die-
5 tary supplement from the representative label
6 provided under subsection (a) with respect to
7 the product name, amount of dietary ingredi-
8 ents, or other distinguishing characteristics
9 such as dosage form (such as pill, capsule, liq-
10 uid, or powder) shall be submitted to the Sec-
11 retary not later than 15 business days after in-
12 troducing the dietary supplement with the
13 change into interstate commerce.

14 “(C) DISCONTINUED DIETARY SUPPLE-
15 MENTS.—If the responsible person has discon-
16 tinued the commercial marketing of a dietary
17 supplement formulation included in a listing
18 submitted by the responsible person under sub-
19 paragraph (A) or (B), the responsible person
20 shall report to the Secretary the date of such
21 discontinuance, within 90 days of the dis-
22 continuance of the dietary supplement.

23 “(5) SUPPLIER INFORMATION RECORD KEEPING
24 REQUIREMENT.—Each responsible person subject to
25 the requirements of this subsection shall maintain a

1 record of the full business name and address from
2 which the responsible person receives any dietary in-
3 gredient or combination of dietary ingredients that
4 the responsible person uses in the manufacture of
5 the dietary supplement, or, if applicable, from which
6 the responsible person receives the dietary supple-
7 ment. The responsible person shall make this infor-
8 mation available to the Secretary within 72 hours of
9 request from the Secretary.

10 “(c) ELECTRONIC DATABASE.—Beginning not later
11 than 2 years after the Secretary specifies a unique dietary
12 supplement identifier system pursuant to subsection
13 (b)(3), the Secretary shall maintain an electronic database
14 that—

15 “(1) is publicly accessible;
16 “(2) is populated with information regarding di-
17 etary supplements that is provided under this section
18 or any other provision of this Act; and

19 “(3) enables the public to search the database
20 by a dietary supplement’s unique dietary supplement
21 identifier or other field of information or combina-
22 tion of fields.

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—For
24 purposes of conducting activities under this section and
25 hiring personnel to carry out this section, there are au-

1 thorized to be appropriated \$4,000,000 for fiscal year
2 2022 and \$1,000,000 for each of fiscal years 2023
3 through 2026.”.

4 (b) MISBRANDING.—Section 403 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
6 ed by adding at the end the following:

7 “(z) If it is a dietary supplement for which a respon-
8 sible person is required to file a listing under section 403D
9 and such responsible person has not made a listing with
10 respect to such dietary supplement.”.

11 (c) NEW PROHIBITED ACT.—Section 301 of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
13 amended by adding at the end the following:

14 “(fff) The introduction or delivery for introduction
15 into interstate commerce of a dietary supplement that has
16 been prepared, packed, or held using the assistance of, or
17 at the direction of, a person debarred under section 306.”.

18 (d) RULE OF CONSTRUCTION.—Nothing in the
19 amendments made by subsections (a) through subsection
20 (c) shall be construed to expand the existing authorities
21 of the Food and Drug Administration, other than as speci-
22 fied in such amendments. This subsection shall not be con-
23 strued to—

24 (1) limit the existing authorities of the Food
25 and Drug Administration; or

1 (2) limit the authorities specified in the amend-
2 ments made by subsections (a) through subsection
3 (c).

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